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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/252,828	02/19/1999	KE-WEN DONG	024754/0114	4940

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EXAMINER
COOK, LISA V

ART UNIT	PAPER NUMBER
1641	28

DATE MAILED: 01/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/252,828	DONG ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-38,40 and 42-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-38,40 and 42-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's response to the Restriction Requirement mailed 8/28/01 is acknowledged. Applicants provisionally elected Group I (claims 25, 26, 34-36, 42, and 43) with traverse (paper#27, filed 10/29/01). The restriction is traversed because all the claims as presently amended in paper #27 recite SEQ ID NO 2 only. The amendment directing all the claims to a single sequence (Seq. Id. No.2) has made MOOT the Restriction Requirement. The Restriction Requirement is therefore withdrawn.

2. Currently, Claims 25-38, 40 and 42-47 are pending and under consideration.

OBJECTIONS WITHDRAWN

Priority

3. This application has been amended to contain the required first sentence of the specification referencing the provisional priority document 60/075,079 filed 12/19/98. Therein obviating the objection.

Specification

4. In the specification abbreviation "Id." has been replaced with a more specific reference. The objection is withdrawn.

Claim Objections

5. Claim 2 is objected to because of the following informalities: The claim refers to the "glycoprotein" of claim 1, while claim 1 and all other claims in the instant application recite a "glycopolypeptide". Although it is recognized that the terms could be utilized interchangeable, it is suggested that one term be consistently employed for clarity. Claim 2 has been cancelled therein obviating the claim objection.

OBJECTIONS MAINTAINED

Drawings

6. The drawings in this application are objected to by the Draftsperson under 37 CFR 1.84 or 1.152 (see PTO-948). Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect may be deferred until after the examiner has considered the proposed drawing correction. Failure to timely submit the proposed drawing correction will result in the abandonment of the application.

Information Disclosure Statement

7. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on form 1449 has cited the references they have not been considered.

Applicant stated that an Information Disclosure Statement was filed in response to the examiner request (paper #12,filed 6/28/00), however no record of such IDS is found in the instant application. Applicant is invited to re submit the papers.

Oath/Declaration

8. A new oath or declaration is required because the date inventor Ke-Wen Dong signed the oath/Declaration is not provided. The wording of an oath or declaration cannot be amended. If the wording is not correct or if all of the required affirmations have not been made or if it has not been properly subscribed to, a new oath or declaration is required. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

Applicant stated that a new declaration and oath was filed in response to the examiner request (paper #12,filed 6/28/00), however no record of a new declaration and oath is found in the instant application. Applicant is invited to re submit the papers.

REJECTIONS WITHDRAWN

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain patent therefore subject to the conditions and requirements of this title.

9. Claims 2 and 6-11 (new claims 25-33, 37, 38, 40 and 42-42) are directed to non-statutory subject matter. There is no recitation of isolation or purification. Therefore, the claimed gycoprotein and/or glycopolypeptide read on naturally occurring materials, which are considered to be non-statutory and non-patentable subject matter within the scope of 35 U.S.C. 101. See Official gazette, 1077 O.G. 24, April 21, 1987. It is recommended that the claims incorporate the claim language, "isolated or purified" to overcome this rejection.

Applicant has included the term "purified" and stated that the smaller polypeptides of claims 38-40 are not found in nature. The rejection is withdrawn.

NEW GROUNDS OF REJECTION NECESSITAED BY AMENDMENT

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 25-38, 40, and 42-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 42, 44, and 45 are vague and indefinite because it is unclear as to what the term "acrosome reaction" entails. The claim recites a glycopolypeptide that can strongly bind human spermatozoa and induce an acrosome reaction in the spermatozoa. Because the term is not defined in the disclosure, the metes and bound of the claim can not be determined. Is it applicant's intent to define any event involving a spermatozoon that releases an egg-penetrating enzyme? Please define.

B. Claims 27, 34, 37, 38, 40, 42, 44, and 45 are vague and indefinite because it is unclear it the glycopolypeptide binds to human sperm or not? The use of the term "can binds" and/or "can simulate" renders the claim indefinite. Does the glycopolypetide bind or not? Does the glycopolypetide simulate or not?

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

I. Claims 25-38, 40, and 42-47 are rejected under 35 U.S.C. 102(b)(e) as being anticipated by Dean (U.S.Patent#5,641,487).

Dean disclosed a polypeptide and functional derivatives thereof which have human ZP3 activity or human ZP3 antigenicity. The polypeptides can be produced either synthetically or by recombinant DNA technology. Specifically, the polypeptide to be expressed is coded for by a DNA sequence or more accurately a nucleic acid sequence. The nucleic acid sequence is optionally transcribed and translated to the target polypeptide via cloning into a vector transformed into a host cell. The vector may be self-replicating or it may integrate into the DNA of the host. (see abstract, claims, and columns 1-4).

The resulting glycopolypeptides produced in this invention comprised several amino acid lengths and they were found to be 97.1% homologous with the instant invention product in SEQ ID NO:2. (MPSRCH comparing protein-protein database search utilizing BLOSUM62 – GenCore version 4.5).

II. Claims 25-38, 40, and 42-47 are rejected under 35 U.S.C. 102(b)(e) as being anticipated by Dean (U.S.Patent#5,672,488).

Dean disclosed a polypeptide and functional derivatives thereof which have human ZP3 activity or human ZP3 antigenicity. The polypeptides can be produced either synthetically or by recombinant DNA technology. Specifically, the polypeptide to be expressed is coded for by a DNA sequence or more accurately a nucleic acid sequence. The nucleic acid sequence is optionally transcribed and translated to the target polypeptide via cloning into a vector transformed into a host cell. The vector may be self-replicating or it may integrate into the DNA of the host. (see abstract, claims, and columns 1-4).

The resulting glycopolypeptides produced in this invention comprised several amino acid lengths and they were found to be 97.1% homologous with the instant invention product in SEQ ID NO:2. (MPSRCH comparing protein-protein database search utilizing BLOSUM62 – GenCore version 4.5).

Response to Arguments

In response to applicant argument that no prima facie case of obviousness has been established with regard to "a glycopolypeptide that can bind human spermatozoa at least 10 times as strong as an equivalent molar amount of mouse ZP3", it is noted that the cited references disclose sequence identification number 2. The functional language of applicants claim do not render the claim patentable over the prior art.

The functional recitation has not been given patentable weight because it is narrative in form. In order to be given patentable weight, a functional recitation must be expressed as a "means" for performing the specified function, as set forth in 35 USC § 112, 6th paragraph, and must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language. *In re Fuller*, 1929 C.D. 172; 388 O.G. 279.

Further, it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dean (U.S.Patent#5,641,487) or Dean (U.S.Patent#5,672,488) in view of Chamberlin et al. (Proc.Natl.Acad.Sci.USA, Developmental Biology, Vol.87, pp.6014-6018, August 1990) and in further view of Stern et al. (U.S.patent#5,869,053).

Please see previous discussions of Dean(5,641,487) and Dean(5,672,488) as set forth above.

Dean(5,641,487) and Dean(5,672,488) differ from the instant invention in not identifying the specific full-length structure of Human ZP3 cDNA and the specific transducing cell line of the PA-1.

However, Chamberlin et al. disclose this limitation in the reference found in the Proc.Natl.Acad.Sci.USA, Developmental Biology, Vol.87, pp.6014-6018, August 1990. The full-length was previously established in this teaching. Chamberlin et al. take advantage of the cross-hybridization of the mouse cDNA and human DNA to isolate and characterize the full-length cDNA clones of human ZP3 (deposited in the GenBank data base-accession no.M35109). Human ZP3 cDNA was purified from total RNA isolated from a human ovary and used as the first-strand synthesis with oligonucleotide primer A2T15. The first-strand was amplified by PCR.

Further, the utility of the PA-1 (human ovarian carcinoma) cell line in PCR techniques involving glycoproteins was also established. In the patent of Stern et al. the glycoprotein 5T4 was identified in human trophoblast. In table III, the reactivity of MAB 5T4 with normal cells and transformed cell lines in cell-surface immunofluorescence and radiobinding assays showed a comparatively high binding index (4.9 in the Ovary cell PA-1. A comparison of reactivity with negative control xenogeneic cell lines indicated positive expression of the antigen. (Column 8, lines 52-61)

Dean(5,641,487), Dean(5,672,488), Chamberlin et al., and Stern et al. are analogous art because they are from the same field of endeavor, all the cited inventions teach method involving glycoprotein production and isolation techniques.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the ovarian cell line PA-1 and human ZP3 as taught by Chamberlin et al., and Stern et al. in either method of Dean(5,641,487) and Dean(5,672,488) to perform glycoprotein production via the transduction of a human ovarian cell line with a polynucleotide that encodes a polypeptide comprising ZP3 because such methods of evaluation as taught by Chamberlin et al., and Stern et al. is well known in the art. A person of ordinary skill in the art would have had a reasonable expectation of success utilizing such techniques, because both the PA-1 cell line and the full-length human ZP3 sequence were established in the prior art.

The motivation to utilize such compounds can be found in the predictable glycosylation sites of ZP3 and its homology to the mouse analogue, which has strong binding affinity for spermatozoa and induces an acrosome reaction.

Response to Arguments

In response to applicant argument that no prima facie case of obviousness has been established with regard to "a glycopolypeptide that can bind human spermatozoa at least 10 times as strong as an equivalent molar amount of mouse ZP3", it is noted that the cited references disclose sequence identification number 2. The functional language of applicants claim do not render the claim patentable over the prior art.

The functional recitation has not been given patentable weight because it is narrative in form. In order to be given patentable weight, a functional recitation must be expressed as a "means" for performing the specified function, as set forth in 35 USC § 112, 6th paragraph, and must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language. *In re Fuller*, 1929 C.D. 172; 388 O.G. 279.

Further, it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

In response to the argument that the reference of Stern et al. teaches away from the instant invention and is applied in hindsight it is noted arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Stern et al. were merely cited to establish that the PA-1 cell line was previously disclosed in the prior art.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

13. For reasons aforementioned, no claims are allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 308-4242, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Lisa V. Cook

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1/9/01

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